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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,949	09/10/2001	Johan Stenflo	003300-816	9510
7590	12/30/2003		EXAMINER	
Benton S Duffett JR Burns Doane Swecker & Mathis PO Box 1404 Alexandria, VA 22314-1404			CHEU, CHANGHWA J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/890,949	STENFLO, JOHAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 November 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-26 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of group II, claims 1-7, 15-16, 20-21 and 24-25 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that there is a technical relationship among different groups, and search for group I-III could be done simultaneously. The reasoning is found persuasive, therefore, groups I-III, claims 1-26 are all under current examination.

***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
3. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protein kinase C inhibitor or alpha-antitrypsin, does not reasonably provide enablement for any inhibitor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The instant invention claim 1, step (i), recites a monoclonal antibody "having specific affinity for a complex between a serine proteinase and *an* inhibitor thereof." It is

believed that applicant refers to inhibitor of the serine proteinase. Nevertheless, the specification only provides one example on the asserted characteristics, namely protein C inhibitor (PCI). (See Figure 1-3, page 11, last paragraph; page 12, third and fourth paragraph) Given the specific features of the monoclonal antibody recited in this invention, i.e. having affinity to both the complex of inhibitor/proteinase, and a cleaved/uncomplexed form of the inhibitor, the instant invention is entitled to the scope within the workable example, i.e. serine proteinase inhibitor (PCI), not with any protein inhibitor. Similarly, claims 2, 6 and 22 share the same problem as claim 1.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, step (ii), “a cleaved and uncomplexed form of said inhibitor” is vague and indefinite. It is unclear what constitutes “a cleaved’ form. Similarly, claim 22 shares the same problem.

With respect to claim 1, line 8, “while having substantially no specific affinity for said inhibitor” is vague and indefinite. It is unclear what constitutes “substantially no specific affinity for said inhibitor.”

With respect to claim 1, line 10, “derivative thereof” is vague and indefinite. It is unclear what is “derivative” in the context, e.g. chemical modification, or recombinant substitution.

With respect to claim 12, "a suitable enzyme" is vague and indefinite. It is not clear what constitutes "suitable" in this context.

With respect to claim 14, "a similar lanthanide" is vague and indefinite. It is unclear what is the "similar lanthanide."

***Conclusion***

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

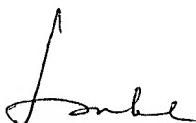
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu  
Examiner



Art Unit 1641

December 16, 2003



LONG V. LE  
SUPERIORITY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

12/24/03